UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

CUREVAC SE (f/k/a CUREVAC AG) and CUREVAC MANUFACTURING GMBH,

Plaintiffs,

v. **Civil Action No. 2:23-cv-222**

BIONTECH SE, BIONTECH MANUFACTURING GMBH, and PFIZER, INC.,

Defendants.

MEMORANDUM ORDER

In their tenth Motion in Limine, (ECF No. 599), Defendants BioNTech SE, BioNTech Manufacturing GMBH, and Pfizer, Inc. ("BioNTech") moved to preclude testimony from Plaintiffs' CureVac SE and CureVac Manufacturing GMBH ("CureVac"), expert, Dr. Nikolay Dokholyan. BioNTech claims Dr. Dokholyan failed to disclose opinions, or the basis for opinions establishing a nexus between the '686 patent's specification of a particular mutation, known as D614G, and surprising and unexpected results he describes elsewhere in his report. Mem. Supp. BioNTech & Pfizer's Mot. in Limine No. 10 Exclude Undisclosed Opinions from Dr. Dokholyan ("BioNTech's No. 10 Mem.") (ECF No. 601, at 3) (sealed version). BioNTech argues that Dr. Dokholyan's disclosed nexus opinions are addressed in a single paragraph of his report, and that his deposition testimony more broadly suggests such a nexus based on scientific literature and "computational modeling," which Dr. Dokholyan allegedly failed to produce. Id. at 3-4.

CureVac opposes the motion, observing that Dr. Dokholyan's rebuttal report describing his nexus opinions expressly incorporated the challenged material, and that his detailed rebuttal

report provided the formulas and methods Dr. Dokholyan used to arrive at his opinion that a POSA would have found the D614G mutation destabilizing. CureVac's Opp'n Defs.' Mot. in Limine No. 10 ("CureVac's No. 10 Opp'n") (ECF No. 708-15, at 1). CureVac argues that Dr. Dokholyan expressly relied on this same evidence to support his claims of a nexus. Id. at 2-3. After reviewing the parties' arguments and Dr. Dokholyan's report and deposition testimony in detail, I agree with CureVac that his opinions regarding nexus are adequately disclosed in the materials provided and that BioNTech had ample opportunity to explore them in his deposition. Accordingly, as explained briefly below, the court DENIES BioNTech's Motion in Limine No. 10. (ECF No. 599).

ANALYSIS

Excluding evidence for failure to timely disclose it as required by Rule 26(a) is a discovery sanction under Rule 37(c) within the court's discretion. S. States Rack & Fixture, Inc. v. Sherwin-Williams Co., 318 F.3d 592, 595 (4th Cir. 2003); see Fed. R. Civ. P. 26(a)(2)(B) (stating that an expert report must contain a complete statement of all opinions witness will express, facts or data witness considered, and any exhibits used to support expert's opinions). However, "Rule 37(c)(1) provides two exceptions to the general rule excluding evidence that a party seeks to offer but has failed to properly disclose: (1) when the failure to disclose is 'substantial[ly] justifi[ed],' and (2) when the nondisclosure is 'harmless.'" Id. at 596 (alterations in original).

Courts in the Fourth Circuit generally address these two exceptions together by applying the five-factor test adopted in Southern States. See id. at 596-97; Zaklit v. Glob. Linguist Sols., LLC, No. 1:14-cv-314, 2014 WL 4925780, at *4 (E.D. Va. Sept. 30, 2014); Rambus, Inc. v. Infineon Techs. AG, 145 F. Supp. 2d 721, 726-27 (E.D. Va. 2001); Swimways Corp. & VAP Creative, LTD v. Zuru, Inc., No. 2:13-cv-334, 2014 WL 12573390, at *2-4 (E.D. Va. July 10, 2014). But the court is "not required to tick through each of the Southern States factors. Southern

States explains that district courts have 'broad discretion' to decide harmlessness and 'should' – not 'shall' – 'be guided by' the five factors." Wilkins v. Montgomery, 751 F.3d 214, 222 (4th Cir. 2014). Those factors are:

> (1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence.

S. States, 318 F.3d at 597.

Dr. Dokholyan's rebuttal report responds to the testimony of BioNTech expert, Dr. Ward, who asserted that the claims of the '686 patent, including the D614G mutation, would have been obvious based on the prior art. See Ward Rpt. Ex. 1 (ECF No. 491-10, §§ VIII, IX) (sealed version). Dr. Dokholyan, among other opinions, argues that a POSA would not have been motivated to pursue the D614G mutation, and would have instead found it was likely to be destabilizing. Dokholyan Rebuttal Ex. 2 (ECF No. 601-2, ¶¶ 30-32, 43, 84-87) (sealed version). A separately-captioned section of his report points to unexpected and surprising results indicating that incorporating the mutation would not have been obvious to a POSA in February 2020, when CureVac applied for the '686 patent. Id. ¶¶ 131-36. As objective evidence of this conclusion, Dr. Dokholyan points to unexpected and surprising results in experiments conducted by Dr. Mehul Suthar, another CureVac expert. Id. ¶ 133. BioNTech attorneys examined Dr. Dokholyan extensively on his opinions concerning the Suthar report and concede that he may testify to his opinion relying on its data. See, e.g., Dokholyan Dep. Ex. 1 (ECF No. 601-1, 32:17-34:17, 37:5-41:20); BioNTech's No. 10 Mem. (ECF No. 601, at 3-5). However, BioNTech claims additional testimony provided in deposition indicates Dr. Dokholyan will rely on additional bases for his opinion that the mutation would produce unexpected and surprising results. BioNTech's No. 10 Mem. (ECF No. 601, at 3-5) (citing Dokholyan Dep. Ex. 1 (ECF No. 601-1, 40:15-41:20, 139:19-

147:9)). Calling them "undisclosed 'nexus' opinions," BioNTech seeks to limit Dr. Dokholyan's testimony exclusively to the Suthar study. Id. at 3, 8.

But as CureVac notes, other paragraphs of Dr. Dr. Dokholyan's nexus opinion expressly link his rebuttal opinions regarding the destabilizing nature of the D614G mutation to his nexus opinions. Dokholyan Rebuttal Ex. 2 (ECF No. 601-2, ¶ 136) ("For all the reasons I described above with regard to the motivations of a POSA with regard to modifying the prior art to incorporate the D614G mutation make it all the more surprising and unexpected that the claimed mRNA-based vaccine molecule results in higher neutralizing antibody titers . . . ."). During his deposition, BioNTech explored these additional elements of his testimony in detail. See, e.g., Dokholyan Dep. Ex. 1 (ECF No. 601-1, 32:17-34:17, 37:5-41:20, 85:8-89:3, 110:11-114:9, 139:19-147:9). And as CureVac notes, Dr. Dokholyan was responding to Dr. Ward's claim that CureVac had not demonstrated or addressed evidence of nexus with regard to the secondary considerations. The same evidence he offered to rebut Dr. Ward's contention that the D614G was obvious may support his claim that the result of Dr. Suthar's experimentation and the superior immune response generated by the D614G mutation were surprising and unexpected. Indeed, that is precisely what Dr. Dokholyan says in his 60-page rebuttal.

As a secondary argument, BioNTech contends that Dr. Dokholyan's opinions on the destabilizing nature of the D614G mutation must be excluded because he premised his opinions on computational modeling or scientific articles not disclosed in his report. BioNTech's No. 10 Mem. (ECF No. 601, at 6-8). But CureVac withheld no computational models supporting Dr. Dokholyan's opinions. In its response to this motion, CureVac recites the precise formulas Dr. Dokholyan applied, all of which are disclosed in his rebuttal report. CureVac's No. 10 Opp'n (ECF No. 708-15, at 5) (citing Dokholyan Rebuttal Ex. 2 (ECF No. 601-2, ¶¶ 30-32, 43, 84-87)

(describing calculations used to compare ΔG of the original protein with the ΔG of the mutated protein). Dr. Dokholyan specifically observes that comparing the ΔG with the D614G mutation to the amino acid position in the original SARS-CoV-1 would have resulted in a 1.6 kcal/mol ΔG, which he described as destabilizing. Dokholyan Rebuttal Ex. 2 (ECF No. 601-2, ¶ 87).

It is true that certain testimony in Dr. Dokholyan's deposition suggests that he may have prepared a report regarding this calculation. However, read in context, it is clear that Dr. Dokholyan did not rely on a separate computational model. Dokholyan Dep. Ex. 1 (ECF No. 601-1, 104:16-105:17) (A: "I was asked what would be the number. I calculated the number. . . . What do you mean by 'report'? Like, if you ask me a question, I report to you the answer. So it is a report."). As CureVac's opposition reaffirms, Dr. Dokholyan does not intend to rely on any opinions not already disclosed in his rebuttal report. In addition, it appears that Dr. Dokholyan set forth the formula and calculation for his opinion that the D614G mutation would be destabilizing in his original rebuttal filed in October 2024. See Dokholyan Rebuttal Ex. 2 (ECF No. 601-2, ¶¶ 30-32, 43, 84-87).

Finally, to the extent Dr. Dokholyan failed to sufficiently specify his calculations, the time for raising that shortcoming has passed. The report and its formulas and calculations has been part of the discovery record for four months, and Dr. Ward had an opportunity to respond to Dr. Dokholyan's opinions—and did so, specifically citing the calculations on which they were based. Ward Reply Ex. 2 (ECF No. 491-11, ¶¶ 223-24) ("[T]he result of such a calculation would have been a very small difference relative to the entire spike protein, and certainly not enough for a POSA to have stopped pursuing variants, especially in the context of the highly stabilizing 2P background.").

Because Dr. Dokholyan's rebuttal in deposition testimony fully disclosed his opinions concerning his finding of surprising and unexpected results and the claimed invention's D614G mutation, BioNTech's motion to limit his testimony on this subject is DENIED.

IT IS SO ORDERED.

/s/
Douglas E. Miller
United States Magistrate Judge

DOUGLAS E. MILLER
UNITED STATES MAGISTRATE JUDGE

Newport News, Virginia
February 24, 2024